

In view of the foregoing, it can be seen that a device and method for the treatment of urinary incontinence has been provided. The device and method provides for the introduction of an agent into tissue surrounding the urethra to add support to the sphincter muscle. The agent can be introduced into a void created in the tissue by radio frequency ablation and can be heated during introduction into the tissue to prevent solidification of the agent prior to introduction. The agent can be heated by the application of radio frequency or other energy thereto after its introduction into the target volume of tissue if necessary to facilitate solidification of the agent therein. The device and method permits the agent to be simultaneously introduced into a plurality of target volumes within tissue surrounding the urethra.

What is claimed is:

1. A medical device for use in a female human body to deliver an agent to a target volume of tissue including a sphincter muscle which surrounds a urethra in the body to treat urinary incontinence, the urethra formed by a urethral wall extending from a bladder to the exterior of the body, comprising an elongate probe member having proximal and distal extremities and a longitudinal axis, the elongate probe member being sized to be able to enter the urethra and having a length so that when the distal extremity is disposed in the vicinity of the target volume of tissue the proximal extremity is outside of the urethra, the elongate probe member having a passage extending from the proximal extremity to the distal extremity, at least one tubular needle disposed in the passage and having first and second extremities and a flow passageway therein extending longitudinally from the first extremity to at least one opening provided in the second extremity, a control handle secured to the proximal extremity of the elongate probe member, operative means carried by the control handle and connected to the first extremity of the at least one tubular needle for causing movement of the at least one tubular needle in the passage and means carried by the elongate probe member for directing the at least one tubular needle through a curved path extending at an angle to the longitudinal axis as the at least one tubular needle moves in the passage, the tubular needle and the operative means included within means for introducing the agent into the target volume so as to add mechanical support to the sphincter muscle and thus increase the closure forces exerted by the sphincter muscle upon the urethra.

2. A device as in claim 1 wherein the at least one tubular needle is an electrode of an electrically conductive material.

3. A device as in claim 2 together with an insulating sleeve coaxially mounted on the electrically conductive electrode, the operative means connected to the insulating sleeve for causing relative movement between the insulating sleeve and the electrically conductive electrode.

4. A device as in claim 1 wherein the directing means directs the at least one tubular needle radially from the elongate probe member.

5. A device as in claim 1 wherein the at least one tubular needle includes a plurality of side ports in communication with the flow passageway.

6. A device as in claim 1 wherein the at least one tubular needle includes a plurality of tubular needles having second extremities, the operative means connected to the plurality of tubular needles and the directing means causing the tubular needles to extend through a curved path at an angle to the longitudinal axis so as to lie in circumferentially spaced-apart positions in a plane perpendicular to the longitudinal axis.

7. A device as in claim 6 together with a second plurality

of tubular needles having second extremities, the operative means connected to the second plurality of tubular needles and the directing means causing the second plurality of tubular needles to extend through a curved path at an angle to the longitudinal axis so as to lie in circumferentially spaced-apart positions in a second plane perpendicular to the longitudinal axis and longitudinally spaced apart from the first named plane.

8. A device as in claim 1 together with a second tubular needle, the operative means connected to the second tubular needle and the directing means causing the second tubular needle to extend through a curved path at an angle to the longitudinal axis and longitudinally spaced apart, from the curved path of the at least one tubular needle.

9. A medical device for use in a female human body to deliver a crystallizable agent to target volumes of tissue surrounding a urethra therein formed by a urethral wall extending from a bladder to the exterior of the body comprising an elongate probe member having proximal and distal extremities and a longitudinal axis, the elongate probe member being sized to be able to enter the urethra and having a length so that when the distal extremity is disposed in the vicinity of the target volumes of tissue the proximal extremity is outside of the urethra, the elongate probe member having a sidewall and a passage extending from the proximal extremity to the distal extremity and having a plurality of circumferentially spaced-apart openings at the distal extremity extending through the side wall, a plurality of guide cannulas disposed in the passage having first and second end portions, each of the guide cannulas having a lumen extending therethrough from the first end portion to the second end portion and communicating with an opening in the side wall, a tubular radio frequency electrode of an electrically conductive material disposed in each lumen and having a flow passageway extending longitudinally there-through, each tubular radio frequency electrode having a port in communication with the flow passageway and having a sharpened tip, an insulating sleeve coaxially disposed on each of the tubular radio frequency electrodes, a control handle secured to the proximal extremity of the elongate probe member, operative means carried by the control handle and secured to the tubular radio frequency electrodes and the insulating sleeves for causing movement of the tubular radio frequency electrodes and the insulating sleeves in the lumens whereby when the insulating sleeves and the tubular radio frequency electrodes are advanced from the openings in the sidewall under the control of the operative means, the insulating sleeves and the tubular radio frequency electrodes are advanced through the urethral wall so that at least a portion of each tubular radio frequency electrode has been advanced into one of the target volumes and is exposed in the target volume so that when radio frequency energy is supplied to the tubular radio frequency electrodes tissue is ablated in the target volumes surrounding said portions to create a void while the insulating sleeves protect the urethral wall from radio frequency ablation, the operative means and the tubular radio frequency electrodes included within means for introducing the crystallizable agent through the ports into the void in the target volumes of tissue so as to increase the closure forces exertable upon the urethra.

10. A method to deliver an agent to a target volume of tissue surrounding a urethra in a female human body to treat urinary incontinence, the tissue including a sphincter muscle and the urethra formed by a urethral wall extending from a bladder to the exterior of the body, comprising advancing a tubular needle having a free extremity with at least one